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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/324,343 06/02/99 GEERKE

J ARC-2865-R3

HM22/0606

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EXAMINER

SHARAREH, S

ART UNIT

PAPER NUMBER

1616

DATE MAILED:

06/06/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

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Office Action Summary

Application No.

09/324,343

Applicant(s)

Geerke

Examiner

Shahnam Sharareh

Group Art Unit

1616



☒ Responsive to communication(s) filed on Jun 2, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-31 is/are pending in the application

Of the above, claim(s) 1-17 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 18-31 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

Applicant's election with traverse of Group III, claims 18-31 in Paper No. 5 filed on April 24, 2000 is acknowledged. The traversal is on the basis that the examination and the search can be made without serious burden. In reply, Examiner expresses that the claims of Group I and II as indicated in Paper No. 4 are directed to patentably distinct methods, and process steps. Accordingly, as stated in Paper No. 4 filed on February 12, 2000 the requirement is proper and hereby is made **FINAL**. Therefore, claims 1-17 are withdrawn from further consideration because they are directed to a non-elected invention.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 18-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoover et al US Patent 5,464,631.

The instant claims are directed to tablets comprising three layers comprising a first layer containing a drug ingredient without any colorant, a second layer containing a drug and a first colorant, and a third layer containing a second colorant, and methods of preparing thereof.

The policy of the US PTO is to give pending claims their broadest reasonable interpretation. The instant open-ended claims comprise and do not exclude any components or

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steps essential to the operability of the cited prior art patents. In addition, Applicant's attention is drawn to the limitation of the instant second colorant. Accordingly, the instant second colorant may comprise any coloring agent that is distinguishable from no color.

Hoover et al disclose tablet formulations containing a two color partially encapsulated medicament in a caplet form wherein at least one pharmaceutically active material comprise a first colorant, and a second layer which is of a different color (see abstract, col 5 lines 45-52, col 7 lines 8-20.) Further, Hoover disclose methods of producing a two colored caplet wherein said caplet is further coated with a solution consisting of various types of polymers such as polyvinylpyrrolidone or cellulose derivatives (see col 7 lines 39-42.) Therefore, Hoover et al disclose dosage forms that comprise a first layer containing an active drug with a colorant, second layer which is drug free but of different color, and the third coating layer which comprise film-forming material. Finally, Hoover disclose methods wherein said layers are press fitted (see col 6 lines 13-18) Accordingly, Hoover meet the limitations set forth in the instant claims.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was

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commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 18-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoover et al US Patent 5,464,631 in view of Wong et al US Patent 5,785,994.

The instant claims are directed to methods of preparing a three layer tablet comprising the steps of: (a) formulating a first layer formulation containing a drug ingredient and a second layer containing a drug ingredient, wherein one of said first or second layers also containing a first colorant, (b) formulating a third layer containing a second colorant that is distinguishable from first colorant or from no color © compressing the three layers to formulate a solid dosage form.

The teachings of Hoover is discussed above. Wong et al disclose tablet dosage forms comprising three layers wherein first layer is drug free, either first or second layer comprise a colorant such as ferric oxide (see col 17 line 23), and the third layer comprise a colorant (see figure 3, col 16 lines 58-67, col 18 lines 1-42.) The tablet of Wong further comprise an exit port (see col 17 line 56) which is drilled by any means known in the art including laser drilling (see col 15 lines 15-18.) Wong et al also disclose that a wall forming composition may be sprayed onto around the laminates (see col 17 line 51.) Finally, Wong et al disclose that their tablets are prepared by pressing the three layers to form a solid core (see col 19 lines 10-18.) Wong et al,

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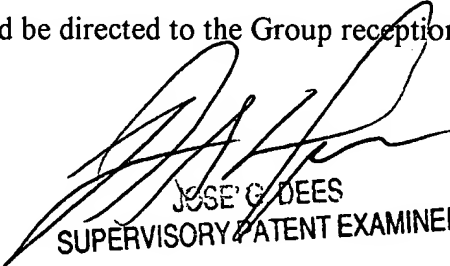
however, fail to specifically disclose the use of various coloring agents in different layers of his tablet.

Although, Hoover does not specifically teach a three layer osmotic dosage form, he suggests that an ordinary skilled in the art may modify his caplet forms to formulate a sustained release dosage form (see col 5 lines 34-44.) Therefore, it would have been obvious to one ordinary skilled in the art to modify Hoover's formulation according to the methods of Wong to formulate a three layer osmotic tablet formulation, because a skilled routiner would have had a reasonable expectation to succeed in formulating dosage forms that provide a sustained release tamper-resistant formulation that possess the physical characteristics of a capsule and allows for easier swallowing and even masking the bitter taste of drugs.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is (703) 306-5400. The examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Jose Dees can be reached on 703-308-4628. The fax phone number for this Group is 703-308-4556. Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 703-308-1235.

sjs 5/31/00


JOSE G. DEES
SUPERVISORY PATENT EXAMINER
1616